December 23, 2009

pSivida Announces Positive Results from the Two Phase 3 FAME(TM) Trials of Iluvien(R) in Patients with Diabetic Macular Edema

More patients receiving either the High Dose or Low Dose Iluvien showed improvement in best corrected visual acuity of 15 or more letters at 2 years compared to those receiving sham treatment. This was statistically significant.pSivida's licensee, Alimera Sciences, plans to file New Drug Application (NDA) in the second quarter of 2010.

WATERTOWN, Mass., Dec 23, 2009 (BUSINESS WIRE) -- pSivida Corp. (NASDAQ:PSDV)(ASX:PVA)(FF:PV3), a drug delivery company with two of the only three ophthalmic sustained release delivery products approved by the FDA for treatment of back of the eye diseases, today reported top-line 24 month results from the Phase III FAME™ study of Iluvien® for the treatment of Diabetic Macular Edema (DME) being conducted by pSivida's collaborative partner Alimera Sciences. The Company will host a conference call and webcast today at 4:30 pm Eastern Time (details follow below). More detailed information is available in the Company's Form 8-K filed today with the Securities & Exchange Commission.

The FAME study was designed as two Phase 3 pivotal clinical trials (Trial A and Trial B). 956 patients with DME were enrolled and randomized to receive either a high dose Iluvien (0.45 ug/day), a low dose Iluvien (0.23 ug/day) or a sham insertion. The primary efficacy endpoint for the FAME Study is the difference in the percentage of patients whose best corrected visual acuity (BCVA) improved by 15 or more letters from baseline on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart at month 24 between the treatment and control groups.

Based on Alimera's analysis of the Full Analysis Set, as described by the International Conference on Harmonization (ICH) Guidance E9 and adopted by the FDA, the primary efficacy endpoint was met with statistical significance for both doses of Iluvien in each of Trial A and Trial B, as well as on a combined basis, as shown below:

	Trial A			Trial B			Combined		
	Individual	**Percentage**	**p-value**	**Individual**	**Percentage**	**p-value**	**Individual**	**Percentage**	**p-value**
Control	14/95	14.7%	--	16/90	17.8%	--	30/185	16.2%	--
Low Dose	51/190	26.8%	0.029	57/186	30.6%	0.030	108/376	28.7%	0.002
High Dose	51/196	26.0%	0.034	62/199	31.2%	0.027	113/395	28.6%	0.002

The Full Analysis Set includes all 956 patients randomized into the FAME Study, with data imputation employed using Last Observation Carried Forward (LOCF) for data missing because of patients who discontinued the trial or were unavailable for follow up. This data set is commonly referred to as the "intent to treat" population.

In addition, both the low and high dose Iluvien showed greater numerical efficacy at month 24 than at month 18, a requirement for approval with 24 month data.

Safety was assessed from all patients enrolled in the study. Intraocular pressure (IOP) increases to 30 millimeters of mercury (mmHg) or greater at any time point, a key adverse event studied in the trial, were seen in 21.6% of the high dose patients and 16.3% of the low dose patients. Over the 24 month period 5.1% of patients receiving the high dose and 2.1% of the patients receiving the low dose had received a trabeculectomy (filter surgery) to reduce their eye pressure.

Based on these and other data, Alimera plans to file for approval of the low dose of Iluvien for the treatment of DME in the second quarter of 2010, followed by registration filings in various European countries and Canada. Submission of the NDA will be based on the month 24 safety and efficacy data while the FAME Study will continue to month 36.

"We are very encouraged by these data and look forward to our collaborative partner Alimera filing the NDA for potentially the first ophthalmic drug therapy approved for DME," said Dr. Paul Ashton, President and CEO of pSivida. "These data further validate our drug delivery technology."

In addition to the analysis described above, as prospectively planned in the protocol, Alimera also conducted several other analyses of the 24 month data. These included (a) an All Randomized and Treated (ART) analysis of the 24 month data that includes data from all subjects randomized and treated and imputes values for all missing data using the LOCF method and (b) a Modified ART analysis that utilizes the ART population but excludes data collected subsequent to the use of treatments prohibited by protocol (such as intravitreal injections of Avastin, Lucentis or triamcinolone acetonide) with the last observation prior to protocol violation imputed to month 24 using the LOCF method. The results of these separate analyses are described below:

By the ART analysis, in Trial A 26.8% of low dose patients and 26.2% of high dose patients gained 15 or more letters at 24 months compared with 14.7% of patients randomized to control (p = 0.029 and 0.032, respectively). In Trial B of the ART analysis 30.8% of low dose patients and 31.3% of high dose patients gained 15 or more letters compared with 17.8% of control patients (p = 0.028 and 0.026, respectively). The results for both doses in both trials were statistically significant. By the Modified ART method, in Trial A 22.6% of patients in the low dose and 24.1% of patients in the high dose gained 15 or more letters compared with 12.6% of control patients (p = 0.057 and 0.026, respectively). Trial A was not statistically significant for either dose. In Trial B by Modified ART, 29.7% of patients in the low dose and 29.3% of patients in the high dose gained 15 or more

letters compared with 13.3% of control patients (p = 0.004 and 0.005, respectively). The results for both doses were statistically significant.

The FAME study protocol provides that the primary assessment of efficacy will be based on the Modified ART dataset and that the other datasets will be considered secondary; the protocol did not specify the Full Analysis Set as a dataset for analyzing the study. However, we believe that the FDA will consider the Full Analysis Set to be the most relevant population for determining safety and efficacy in Trials A and B.

"We look forward to the continued benefits of our agreement with Alimera, including a $25 million milestone payment that would be due on approval of Iluvien, profit participation on sales of Iluvien and payment of the $15 million conditional note from Alimera. If the note is not paid by April 2010, the annual interest rate increases to 20% (to be paid quarterly) and Alimera is to begin monthly principal payments of $500,000," Dr. Ashton continued.

More detailed analyses will be presented in February 2010 at the Angiogenesis, Exudation and Degeneration 2010 Meeting in Miami, Florida.

Conference Call Information

pSivida will host a conference call and live webcast to discuss the FAME Study results at 4:30 p.m. ET today, December 23, 2009. The conference call may be accessed by dialing (800) 901-5218 from the U.S. and Canada, or (617) 786-4511 from international locations, passcode 11287634. Listeners are encouraged to login at least 15 minutes prior to the start of the scheduled presentation to register, download and install any necessary audio software.

A replay of the call will be available approximately two hours following the end of the call through December 30, 2009. The replay may be accessed by dialing (888) 286-8010 within the U.S. and Canada or (617) 801-6888 from international locations, passcode 28531673.

The conference call will also be available via the internet at http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.psivida.com&esheet=6126496&lan=en_US&anchor=www.psivida.com&index=1&md5=42cc5763b91bf55eccc617c820f24835 and will be distributed through the Thomson StreetEvents Network. Individual investors can listen to the call via http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.earnings.com&esheet=6126496&lan=en_US&anchor=www.earnings.com&index=2&md5=16f32f27e8fde71938332c714789d08b and Institutional investors can access the call via http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.streetevents.com&esheet=6126496&lan=en_US&anchor=www.streetevents.com&index=3&md5=8cfcf5e27ba01b858317d5fcddc97e33. The call will be archived and accessible on the Web site for approximately 30 days.

About the FAME Study

The Phase 3 FAME Study consists of two multi-center, randomized, double-masked trials for Iluvien in sites across the United States, Canada, Europe and India. The two trials have identical protocols and enrolled 956 patients across 101 academic and private practice centers. Patients in each trial were randomly assigned to one of three groups in a 2:2:1 randomization, respectively. One group received a high dose of Iluvien (an approximate initial 0.45 micrograms (ug) per day dose), a second received a low dose of Iluvien (an approximate initial 0.23 micrograms (ug) per day dose) and the third group received sham. The sham included all the steps involved in the insertion procedure with the exception that patients in this group had a blunt inserter without a needle to apply pressure to the anesthetized eye in order to simulate an insertion. This procedure mimics an intravitreal insertion and helps to maintain proper patient masking.

In addition to comparing the incidence of improvement in BCVA of 15 letters or greater from baseline between the treated and control arms, a numerical comparison of improvement of BCVA of 15 or more letters versus baseline was made between the month 24 and month 18 data, within each treatment arm. The results showed that the incidence of improvement at month 24 is numerically greater than that at month 18. Submission of the NDA will be based on the month 24 safety and efficacy data while the study will continue to month 36.

About DME

DME, the primary cause of vision loss associated with diabetic retinopathy, is a disease affecting the macula, the part of the retina responsible for central vision. When the blood vessel leakage of diabetic retinopathy causes swelling in the macula, the condition is called DME. The onset of DME is painless and may go undetected by the patient until it manifests with the blurring of central vision or acute vision loss. The severity of this blurring may range from mild to profound loss of vision. The Wisconsin Epidemiologic Study of Diabetic Retinopathy found that over a ten-year period approximately 19% of diabetics studied were diagnosed with DME. Based on this study and the current U.S. diabetic population, Alimera estimates that there will be an incidence of approximately 340,000 cases of DME annually in the United States. As the population of diabetics increases, Alimera expects the annual incidence of diagnosed DME to increase.

About Iluvien®

Iluvien is an investigative, extended release intravitreal insert that Alimera is developing for the treatment of DME. Each Iluvien insert is designed to provide a therapeutic effect for up to 36 months by delivering sustained sub-microgram levels of fluocinolone acetonide (FA). Iluvien is inserted in the back of the patient's eye to a position that takes advantage of the eye's natural fluid dynamics. Iluvien is inserted with a device that employs a 25-gauge needle, which allows for a self-sealing wound.

About pSivida Corp.

pSivida is a world leader in the development of tiny, sustained release, drug delivery products that are administered by implantation, injection or insertion. pSivida's lead development product delivers fluocinolone acetonide (FA) for the treatment of diabetic macular edema (DME). This product candidate, formerly known as Medidur™ FA for DME, is licensed to Alimera, which is conducting fully-recruited Phase III clinical trials and intends to commercialize the product under the name Iluvien®. pSivida also has two products approved by the Food and Drug Administration (FDA): Retisert® for the treatment of posterior uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. pSivida has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated. pSivida has a worldwide collaborative

research and license agreement with Pfizer Inc. under which Pfizer may develop additional ophthalmic products.

pSivida owns the rights to develop and commercialize a modified form of silicon known as BioSilicon™, which has potential therapeutic applications. The most advanced BioSilicon product candidate, BrachySil™, delivers a therapeutic P32, a radioactive form of phosphorus used to treat cancer, directly to solid tumors. pSivida conducted an initial safety clinical trial of BrachySil for the treatment of pancreatic cancer and in October 2009 completed a follow-on dose-ranging clinical trial.

pSivida's intellectual property portfolio consists of 62 patent families, over 100 granted patents, including patents accepted for issuance, and over 200 patent applications. pSivida conducts its operations from Boston in the United States and Malvern in the United Kingdom.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements. The following are some of the factors that could cause actual results to differ materially from the forward-looking statements: inability to commercialize Iluvien or significant delays in the commercialization of Iluvien; inability to obtain regulatory approvals of Iluvien; failure to achieve an appropriate relationship between the benefits of Iluvien's efficacy and the risks of its side effect profile; regulatory agency imposition of limitations on the uses for which Iluvien may be marketed, subsequent withdrawal of approval or other actions adverse to our business; failure of Iluvien to be granted priority review or receive approval within the six month priority review/approval cycle; continued losses and lack of profitability; inability to derive revenue from Retisert; impairment of intangibles; fluctuations in the fair values of certain outstanding warrants; fluctuations in operating results; inability to raise capital; termination of license agreements; inability to obtain regulatory approvals for products; inability to obtain partners to develop and market products; competition; insufficient third-party reimbursement for products; inability to protect intellectual property or infringement of others' intellectual property; failure to retain key personnel; consolidation in the pharmaceutical and biotechnology industries; failure to comply with laws and regulations; manufacturing problems; risks and costs of international business operations; volatility of stock price; possible dilution through exercise of outstanding warrants and stock options; possible influence by Pfizer; payment of registration penalties; nonpayment of dividends; and other factors that may be described in our filings with the Securities and Exchange Commission. Given these uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

For more information on pSivida, visit http://cts.businesswire.com/ct/CT?id=smartlink&url=http%3A%2F%2Fwww.psivida.com&esheet=6126496&lan=en_US&anchor=www.psivida.com&index=4&md5=765a5c5d676cadb166931eff3adffd3d.

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